

REMARKS

This Amendment is responsive to the Office Action dated April 28, 2009. Claims 44-52 are pending in the application. Applicant would initially like to thank the Examiner for the indication that the prior pending rejections are withdrawn. In the current Office Action, Claims 44-52 stand rejected under 35 U.S.C. §103 as being unpatentable over Carter, U.S. Patent No. 6,478,791 in view of Geitz, U.S. Patent No. 6,592,596. Applicant has carefully reviewed the Office Action and the cited references, and respectfully requests reconsideration of the Claims in view of the remarks presented below.

Rejection of Claim 44 Under 35 U.S.C. §103

Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,478,791 ("Carter") in view of U.S. Patent No. 6,592,596 ("Geitz"). Carter is directed to the provision of therapy for incontinence by selectively reducing an effective length of the endopelvic fascia or other endopelvic support tissues. [Carter, Col. 5, lines 22-25].

"this effective shortening of the endopelvic fascia, together with any stiffening of the fascial structure (through the formation of adhesions, the application of heat or radio frequency potential, or the like) will be sufficient to improve the support of the urethra, bladder neck, and bladder so that incontinence is inhibited." [Col. 7, l. 63 – Col. 8, l. 2]

The endopelvic fascia, which is shortened in the procedure outlined by Carter, is described as by Carter as follows:

"Of particular importance for the method of the present invention, endopelvic fascia EF defines a hammock-like structure which extends between the left and right arcus tendinous fascia pelvis ATFP. These latter structures extend substantially between the anterior and posterior portions

of the pelvis, so that the endopelvic fascia EF largely defines the pelvic floor." [Col. 5, lines 53 – 59]

Carter depicts the endopelvic fascia in Figure 15a, reproduced here:

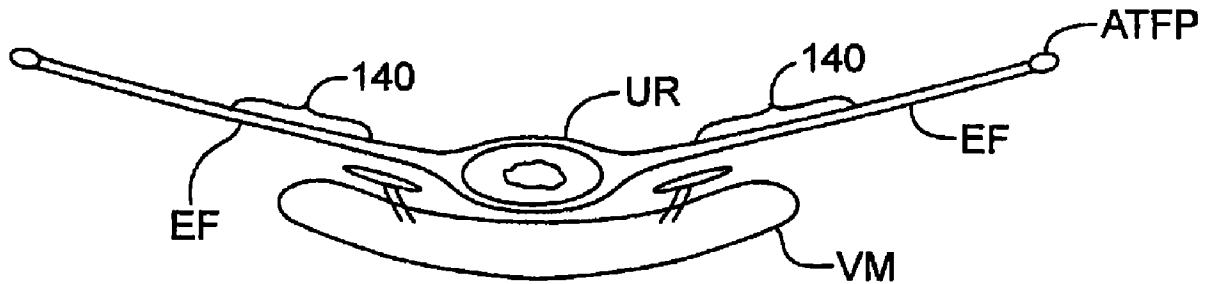


FIG. 15A

As one can see, the endopelvic fascia, **EF**, referred to by Carter as a "hammock-like structure," is a thin tissue stretched between the left and right arcus tendinous fascia pelvis **ATFP**.

Claim 44 is a method claim reciting a series of steps. The Claim is reproduced here for convenience.

44. A method of acquiring tissue from within a hollow body organ, comprising:
- positioning a first acquisition member and a second acquisition member adjacent to a region of tissue within the hollow body organ, wherein the first and second acquisition members are in apposition to one another along a first longitudinal axis in an open configuration;
 - adhering tissue from the region within each of the first and second acquisition members; and
 - compressing the adhered tissue between the first and second acquisition members in a closed configuration.

The Office Action asserts that Carter teaches the foregoing steps of Claim 44, citing to Figure 9A and 9B of Carter. The Office Action contends that the first and

second acquisition members correspond to arms **52**, and that the steps of "adhering tissue from the region within each of the first and second acquisition members" and "compressing the adhered tissue between the first and second acquisition members" are taught by Figure 9. Applicant respectfully disagrees. The discussion of Figure 9 is set forth in two paragraphs of column 8 of Carter, lines 35 – 51. Carter first states that the arms **52** have roughened surfaces **36** to engage and draw the fascia surface inward. As the tissue is moved inward, the fold retainers **54** push the tissue away from the arms into a fold **22**. The arms **52** act in the same manner as the rollers **36** of Figure 8, gripping the surface of the tissue but not "adhering tissue . . . *within* each of the first and second acquisition members" and not "*compressing the adhered tissue.*"

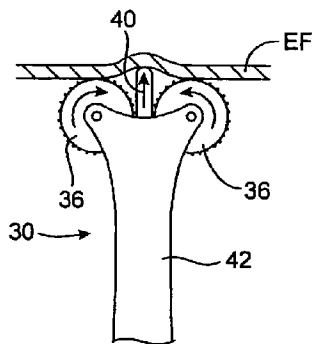


FIG. 8B

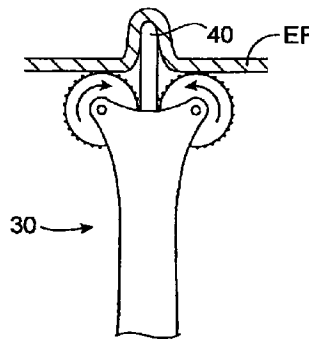


FIG. 8C

The arms of Figure 9A and 9B work like wheels of Figure 8, where the surface **36** "grips" the fascia and moves it while the rod **54** acts like the "retainer" **40** to push the fold of fascia outward. Contrary to the Office Action's assertion, the arms **52** do not compress the tissue, and does not compress the tissue between the first and second acquisition members. Also, there is nothing in the Carter disclosure that establishes the region of tissue occurs "within" the acquisition members, since the surface **36** that grips the fascia in Carter is on the outside of the arm. Moreover, the rod **54** pushes the tissue away from the arms **52** to ensure that the material does not fold between the arms, and there is nothing in Carter's disclosure that suggests, much less teaches, that the arms "compress" the tissue. Because the claimed step is not taught nor suggested by the cited reference, a *prima facie* case of obviousness has not been established.

If the Office Action contends that any of these limitations are still met by the Carter reference, Applicant respectfully requests that a non-final office action be issued explaining:

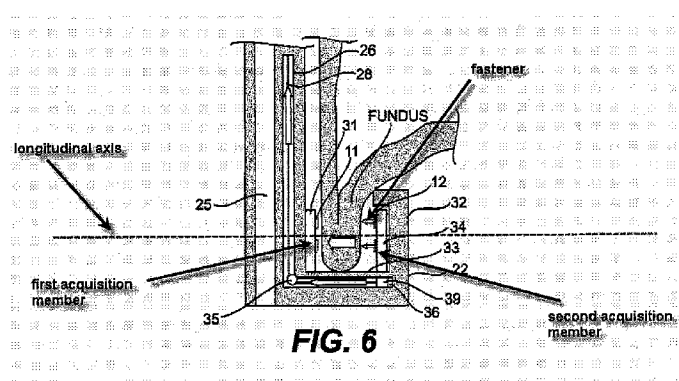
a) where Carter teaches that the endopelvic fascia tissue is "adher[ed] . . . within each of the first and second" arms 52; (Applicant contends it is designed and teaches that the tissue is folded away from the arms) and

b) where Carter teaches that the arms "compress[] the adhered tissue between [them]"; (Applicant can find no disclosure where tissue is *compressed*, and believe that compressing the tissue is contrary to the objects of the Carter method.

Even with the above deficiencies, Carter still admittedly fails to disclose the devices and methods for use "within a hollow body organ" and "advancing the first and second acquisition members transesophageally into the hollow body organ" (Claim 47) The Office Action acknowledges that Carter's method and devices do not teach this portion of the claimed method, but seek to overcome this deficiency by combining the teachings of Geitz. Applicant respectfully submits that Geitz and Carter cannot be combined without the benefit of impermissible hindsight, and even then cannot be combined to yield a *prima facie* case of obviousness.

As set forth above, Carter is concerned with a technique for treating incontinence by shorting the supporting platform that the bladder rests upon, namely the endopelvic fascia. On the other hand, Geitz is directed to a method for securing a tissue fold, for example a fundus wall onto an esophagus wall (Abstract). The Figure (right) shows how Geitz uses a cup-like structure 32 to form a circular or semi-circular fold of tissue.

The structure in profile is "J" shaped to capture tissue that is parallel with the longitudinal



axis of the device. Radial clips are driven into the tissue to create a ring around the lower esophageal sphincter.

Given these two disparate disclosures, the question becomes what methods would be obvious from the combined teachings of these references, assuming *anything* could be gleaned from their combination. Certainly, the objects of the two inventors are completely different and unrelated. The cup-shaped device of Geitz would serve no purpose in trying to solve the incontinence problem of Carter, and Carter's clamping arms would be useless in securing the LES of Geitz. More importantly, Claim 44 is a method claim which recites a series of steps, not apparatus. The Office Action must show that the claimed "steps" are obvious when Geitz is combined with Carter, not the apparatus are obvious to use. When the steps of Claim 44 are properly examined, the Office Action's conclusion that it would have been obvious "to use the device of Carter to create a fold from within a hollow body organ" simply cannot be justified.

The Supreme Court in KSR International v. Teleflex Inc., which is cited by the Office Action, cautioned against the use of hindsight and analysis that is tailored from the Applicant's disclosure: "A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." The Office Action appears to be guilty of this very tactic, where two wholly disparate teachings are combined with no rational or proper basis for utilizing the tools of one to solve the problems of the other, other than that it has been held that "use of a known technique (creating fold within a hollow body organ) to improve similar devices (fold for creating devices) will yield predictable results." O.A., p. 4. There is no analysis provided here. What predictable results? Is the Office Action arguing that Carter's arms 52 could somehow be used in an obvious manner to extend the LES of Geitz? Since Carter's device creates a fold that is exterior to the device, as opposed to Geitz' device which draws tissue into the device, it is unclear how the Office Action is suggesting that Carter's device could be implemented, and what purpose it would serve. If it is inferior to the Geitz' device at solving the Geitz objective, and in fact cannot be used to solve the

problem, would it still be obvious to combine the references. Applicant respectfully submits that it would not, and that the conclusory rationale provided by the Office Action is unsupported in the record and constitutes *ex post* reasoning that the Supreme Court cautioned against.

Conclusion

The combination of Carter and Geitz fails to teach all of the claim limitations of Claim 44, and there suggestion to combine the references is the product of impermissible hindsight. There is no analysis to support the purported combination, merely the platitude that known techniques are interchangeable. When the actual devices and techniques are scrutinized, however, there is no rational or logical reason that one of ordinary skill in the art would apply one teaching to the other, for the tools are used for different purposes and different tasks. Accordingly, the proposed combination is properly withdrawn. There are no outstanding valid rejections of pending Claim 44, and therefore Applicant respectfully submits that the claim is in condition for allowance. The allowance of Claim 44 renders the remaining dependent claims allowable, and early notification of same is requested.

If the Examiner believes that a telephone conference will further the prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is authorized to charge any deficiencies or fees in connection with this amendment to Deposit Account No. 06-2425.

Respectfully submitted,
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